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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94102-7070
Telephone: 510-337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-50212

September 25, 1997

Gilbert R. Teixeira
5601 Mountain View Road
Turlock, California 95380

WARNING LETTER

Dear Mr. Teixeira:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on August 5 and 18, 1997 by Food and Drug Administration (FDA) Investigator Alice A. Blair have revealed serious violations of the Federal Food, Drug, and Cosmetic Act (Act) as follows:

A food is adulterated under Section 402(a)(2)(D) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512 of the Act. On July 2, 1997 you consigned a cull dairy cow (identified by USDA laboratory report number 384733) for sale for slaughter as human food. This cow was delivered for introduction into interstate commerce by your firm, and was adulterated by the presence of illegal tissue residues. USDA analysis of tissues from this animal revealed the presence of streptomycin in the kidney tissues at 2.40 parts per million (ppm). The tolerance level for streptomycin in the kidney tissues of a cow is 2.00 ppm.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.

2. You lack an adequate system for assuring that animals to which you administer medication, such as Quartermaster Penicillin and Dihydrostreptomycin, have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

3. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.

4. You lack an adequate system for assuring animals have been treated only with drugs which have been approved for use in their class of animal or species.

You are adulterating the drug Quartermaster brand Penicillin and Dihydrostreptomycin within the meaning of Section 501(a)(5) of the Act when you do not use this drug in conformance with the approved labeling. Labeling for Quartermaster specifically declares that animals treated with the product are not to be slaughtered for food within sixty days. Failure to adhere to the prescribed withdrawal time is likely the cause of the presence of the illegal levels of streptomycin in the animal you delivered for food use.

Your use of the drug Polyflex a brand of ampicillin is not in conformance with approved labeling directions. Your veterinarian prescribed ampicillin G procaine at 2 mLs per 100 lbs intramuscularly once daily for a period of three to five days. Your practice of administering 10 mLs in a cow is likely to result in harmful residue levels.

Failure to adhere to the instructions on drugs is likely to cause illegal residues and makes the drugs unsafe for use.

We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act.

Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held

for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act and regulations are being met.

Your firm has established a history of offering animals for sale for human food use which have been found to be adulterated due to the presence of drug residues. According to USDA analytical reports, your firm offered seven animals for sale during the period of August 1, 1989 to November 8, 1995, which were found to contain violative levels of antibiotics. As a result, inspections were conducted of your dairy farm by FDA investigators in March and September, 1991, and in December, 1995. Your farm was also inspected by a State of California investigator in August, 1995. During each inspection you were warned that it is illegal to market animals with illegal levels of antibiotics in tissue residues. As a result of the violations found during the inspections conducted by the FDA, warning letters, dated June 25, 1991 and February 6, 1996, were issued to you for each inspection. The State of California issued you notice of warning in August, 1995 as a result of the violations found during their inspection. Also, the U.S. Department of Agriculture sent you a letter for each instance in which their analysis found violative levels of drug residues. You have failed to take adequate corrective action. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen (15) days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should include copies of any available documentation demonstrating that corrections have been made. Please direct your reply to Alice A. Blair, Investigator, U.S. Food and Drug Administration, P.O. Box 1179, Stockton, California 95201.

Sincerely yours,

Charles D. Moss
Acting District Director
San Francisco District